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Message

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Sent: 2/26/2013 12:17:27 PM
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Subject: FW: NACDS Regional Chain Conference Call Summary-February 19th
Attachments: CMS Pharmacy DTS Letter to Jon Blum 2-7-13.pdf.pdf; NACDS Comments DEA Drug Disposal NPRM Feb2013.docx.docx; NACDS Summary HITECH Omnibus Privacy Rule Jan2013.docx.docx

TO: TEXAS FEDERATION OF DRUG STORE MEMBERS

FYI – here is the summary of the NACDS Regional Conference call held this past Tuesday. As I mentioned at the TFDS meeting, it is scheduled on the third Tuesday of each month. The conference number is in the CEO Update that is distributed electronically on Fridays.

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From: Arianna Daoulas

Sent: Thursday, February 21, 2013 2:27 PM

To: Govt Affairs and Public Policy; Don Bell; Mary Ellen Kleiman

Subject: Regional Chain Conference Call Summary-February 19th

Members,

Thank you for participating on Tuesday's Regional Chain Conference Call. Below is a summary of the call. The next call will be held on March 19th. We will speak with you then, if not before.

Arianna Daoulas

Federal Update:

Entitlement Reform:

On March 1, the extension of the sequester expires triggering \$85 billion in FY '13 cuts; the first of over \$1 trillion in cuts to federal discretionary and defense spending over the next nine years. This could impact implementation of the Affordable Care Act, with cuts affecting a variety of programs, including the state health exchanges. The Senate is expected to act on legislation to delay the sequester next week but little time remains for a resolution before March 1. Congress must also act on a new federal budget deal before March 27, as well as the debt limit extension, which was delayed by both the House and Senate until May 18 of this year.

With no negotiations currently taking place between the White House and Congress on a larger budget deal, action is expected in both the House and Senate on budget resolutions and possibly budget reconciliation legislation which could lead to progress on entitlement reform later in the year. NACDS is continuing to meet with congressional offices to discuss entitlement reform in the context of the value of chain pharmacy in maintaining patient access, lowering costs and improving care as healthcare reform is implemented.

MTM:

Senator Hagan's office is still working on draft legislation that would focus specifically on reimbursing MTM services for Medicare Part D beneficiaries who have one chronic condition

Senator Hagan is personally invested in MTM and has been reaching out to her colleagues, Republicans and Democrats to advance legislation to allow CMS to cover additional Part D beneficiaries should those consultations result in added savings to the Part D program. Senator Hagan is planning on introducing the legislation before NACDS RxImpact Day. Representative Cathy McMorris Rodgers is looking to introduce companion legislation in the House of Representatives in that same time frame. Possible vehicles for MTM legislation include compounding legislation that may emerge from the Senate this winter/spring.

Prescription Drug Abuse and Diversion Commission:

NACDS is continuing to pursue a national commission that would be authorized by Congress. Sen. Barbara Boxer (D-CA) has agreed to be the Senate champion of the proposal and is drafting legislation to create it. Her proposal would contain two co-chairs, one representing the law enforcement community and the other representing the healthcare community. She is expected to introduce the legislation in the next few weeks. Sen. Boxer's office will try to include the proposal in compounding legislation that is expected to move this year;

ADUFA may be another vehicle as well. Rep. Tom Marino (R-PA), a member of the House Judiciary Committee, is expected to lead the effort on the commission in the House.

Senator Boxer has shown strong leadership on behalf of patients and community pharmacy, working with her Senate colleagues to both form a Commission as well as a GAO study to look into DEA practices that may imperil legitimate patient access to their needed medications. Senator Boxer and Senator Coburn recently drafted a request letter to GAO for the study and are shopping it to other Senate offices for signatures.

Compounding:

Oversight efforts in both the House and Senate on compounding and the meningitis outbreak connected to the NECC are expected to continue into this year, with the House Energy and Commerce Committee continuing its bipartisan investigation and the Senate HELP Committee to explore marking up compounding legislation in the next few months.

Legislative proposals have been introduced in the House of Representatives. One by Rep. Ed Markey (D-MA), the “Verifying Authority and Legality in Drug (VALID) Compounding Act of 2012” is based on 2007 legislation drafted by Sen. Ted Kennedy (D-MA) and would mandate pharmacies that engage in interstate commerce to register with the FDA, as well as require serious adverse-event reporting. Legislation introduced by Rep. Rosa DeLauro (D-CT) and Rep. Nita Lowey (D-NY), the “Supporting Access to Formulated and Effective Compounded Drugs Act of 2012”, would require that any pharmacy that does compounding would have to register with FDA, unless that pharmacy employs fewer than 20 people and does not ship interstate. The bill also requires compounded products to be labeled as such, and pharmacists would have to make sure that the patient understands that they are getting a compounded medication. In addition, pharmacies and prescribers would have to give patients informational leaflets about their compounded medication. As these office look to reintroduce these bills in the 113th Congress, NACDS staff is working with them to make sure our concerns with the legislation are addressed in the new bill texts.

Supply Chain:

NACDS is working as a member of the PDSA to push for legislation that helps improve the security of the pharmaceutical supply chain.

We are continuing to talk to the Hill about the importance of quick action on supply chain legislation that is both effective and implementable as the requirements for manufacturer serialization under the California Track and Trace law get closer. Federal preemption needs to be an essential part of any legislation that is brought before Congress so we can avoid the inefficiencies and costs chain pharmacy would face by dealing with 50 different regulatory regimes.

Senators Bennet and Burr and Representatives Latta and Matheson are looking at introducing supply chain legislation in the near future to help keep the pressure on Congress to act quickly on supply chain legislation.

DTS:

The Affordable Care Act mandated that by 2016, all areas of the country and all DME items, including retail-provided diabetes testing supplies, will either be part of competitive bidding or will be reimbursed at competitive bidding rates. The change in the reimbursement amount will occur in two phases:

- 1) Beginning April 1, 2013, DTS will be reimbursed at the current DMEPOS Fee Schedule amount for mail order DTS. For a box of test strips, goes from an average of \$38.88 (current non-mail order rate) to an average of \$33.51
- 2) Implementation of the National Mail Order (NMO) on July 1, 2013) paid at the Single Payment amount which should come in at \$10.41

NACDS continues to work with members and other stakeholders to mitigate the extent to which these changes will impact retail pharmacies. We are also working with our past Congressional champions on this issue to send letters into CMS asking them to revisit the rates because of patient access issues.

Hydrocodone Rescheduling:

On January 25, 2013, an FDA advisory panel voted 19-10 to reschedule combination hydrocodone products from a Schedule III to a Schedule II Drug. Members of Congress have also been weighing in on the rescheduling issue. Reps. Vern Buchanan (R-Fla.) and Edward Markey (D-Mass.) wrote to the FDA last week supporting the rescheduling. painkillers containing hydrocodone, such as Vicodin, from a Schedule III to a Schedule II drug. Senator Charles Schumer also announced recently that he was urging the FDA to reschedule combination hydrocodone products as well.

NACDS will continue to discuss its concerns with Members of Congress about the impact reclassification will have on the access pain patients will have to needed medication as well as work with patient and pain care advocacy groups to make sure policy makers understand the impact this move would have on patient care.

Medicare Part B Diabetes Testing Supplies:

The American Taxpayer Relief Act included changes to the reimbursement rate for Medicare Part B diabetes testing supplies. Beginning on April 1, 2013, all diabetes supplies will be reimbursed at a single payment rate. The Taxpayer Relief Act also requires a further reimbursement reduction, setting payment at the National Mail Order rate beginning July 1, 2013. CMS announced the National Mail Order rate shortly after enactment of the American Taxpayer Relief Act, and stakeholders were stunned by the draconian reduction of an average of 72%. NACDS and others continue to push back against this rate. We sent the attached letter to CMS, along with NCPA, and are also meeting with Members of Congress to put pressure on CMS to make changes to the new rate.

Supply Chain Update:

Federal Drug Traceability:

There is continued activity to enact federal legislation to establish a national uniform supply chain drug traceability approach to enhance security. NACDS is actively involved with these activities through work with PDSA (Prescription Drug Security Alliance). The legislative approach being recommended by PDSA would have a stepwise building block approach consisting of an initial interim approach with more definition around the use of drug pedigrees, national wholesaler licensure requirements, and moving into a phase two to evaluate tracing prescription drug product packages at the unit level. This second phase would be informed by pilot studies and supply chain stakeholder and public input. PDSA seeks a federal uniform solution with preemption of state laws including California and Florida. We are waiting for the draft legislative language to be come out from the Senate and House offices working on this to see what they are thinking.

On another note, FDA has advised that they will be releasing standards for track/trace and interoperable systems in 2013

Pharmaceutical hazardous waste disposal:

We are working on several fronts to address and promote a sensible approach on how hazardous waste products from pharmacies, both prescription and other products, must be handled when they leave pharmacies through the reverse distribution system. By way of background, the Environmental Protection Agency (EPA) determines what products are considered hazardous waste and sets the requirements for how they must be handled when they are waste. The key word here is waste. Products that have value are not considered waste. For example, nitroglycerin tablets are not waste as they travel to the pharmacy for distribution through dispensing. However, when they are outdated and being returned for disposal, they would be considered waste. We are expecting EPA

to issue a proposed rule this year that will aid with these issues e.g. considering returned non-dispensable pharmaceuticals to reverse distributors to not be considered waste as they have a “creditable” value.

“Best Practices” for Prescription Container Labels for Blind and Visually Impaired:

As a reminder, a law enacted in 2012 as part of the FDA user fee bills required the US Access Board to convene a stakeholder working group comprised of equal representation from the patient community and the pharmacy community to develop “best practices for pharmacies” for the blind and visually impaired to aid their access to information on prescription container labels. The US Access Board was established many years ago as the federal agency to work on accessibility issues for people with disabilities. The Board has held one in person meeting and one telephone conference call, with an upcoming call for the first week in March. The Board will issue a preliminary report to the work group for comments, and then a final report by July 2013. Subsequently, there will be a GAP Study to start in December 2014 to review pharmacies use of the best practices and whether the barriers to accessible information prescription containers are continuing. In addition, there will be a Comptroller General report by September 2016.

State Government Affairs Update:

In most cases, state legislative sessions currently in process are moving quickly. Virginia will be the first to adjourn at the end of this week followed by Wyoming next week.

State AAC Update:

There are now six states that use average acquisition cost (AAC) as a reimbursement benchmark for both brand and generic drugs. Colorado and Iowa moved to AAC-based reimbursement on February 1st, joining Alabama, Oregon, Idaho and Louisiana.

Biosimilars:

The fastest growing legislative trend relates to biosimilars. Last year, we saw a handful of bills on substitution of biosimilars. This year, we are seeing many more. Two biotech companies are credited for these bills. Generally, these bills include the following provisions:

- substitution should only occur when FDA has designated a product interchangeable,
- the prescriber should be able to prevent the substitution,
- the prescriber should be notified of the substitution,
- the patient should be notified of the substitution and
- the pharmacist and physician should keep a record of the substitution.

Because many states’ generic substitution laws will need to be changed, we are also starting to see some bill language that would to permit substitution of biosimilars without special requirements. The difficulty with this approach is the necessary work of the FDA to permit substitution of biosimilars is in process so there is little to no language available for use at the state level to develop statutes and regulations that will ensure concurrence with FDA policies once they are developed.

For more information about this legislation, contact your NACDS State Government Affairs Director or Sandra Guckian, Vice President, State Government Affairs, at 703.837.4195.

Privacy Update:

HITECH Omnibus Final Rule:

In late January, the Department of Health and Human Services (HHS) issued final rules to implement most of the provisions of the HITECH Act, which was passed by Congress in 2009. This final rules are the most significant modifications to HIPAA since HIPAA went into effect. The final rules are effective March 26, 2013, but compliance is not required until September 23, 2013. A summary of the final rules is

attached. NACDS will host a webinar about the final rules in March, additional information about the webinar will be provided soon.

DEA Update:

DEA Proposed Rule for Drug Disposal:

NACDS submitted the attached comments to DEA on a proposed rule to allow consumers to dispose unused, unwanted controlled substance medications. In the proposed rule, DEA would allow pharmacies to voluntarily offer collection receptacles on site for general consumer use, or off site at long-term care facilities (LTCF) for LTCF patient use. In addition, DEA is proposing to allow consumers to mail their unused, unwanted medications to authorized collectors for destruction and disposal, so long as specially designed mail-back packages are utilized. Although we are supportive of providing options for consumers to rid themselves of unwanted controlled substance medications, we expressed concern to DEA that their proposed requirements for pharmacy collection receptacles are overly burdensome and would serve to discourage pharmacies from providing that option to consumers. We advised DEA that while we appreciate that their proposed rule is voluntary, the DEA rule should enable pharmacies to provide medication disposal services to consumers without being overly restrictive.

FDA Update:

Hydrocodone Rescheduling:

In late January, an FDA advisory panel, comprised of scientific and medical experts, voted to tighten restrictions on combination hydrocodone products such as Vicodin and Lortab, by recommending moving the products to the more restrictive Schedule II classification. The recommendation followed a two-day hearing spurred by 2012 federal legislation and also by a request from DEA. FDA had rejected a similar rescheduling request from DEA in 2008. NACDS testified at the hearing in opposition to rescheduling the products, as did other pharmacy groups, other provider groups, and patient groups. However, the advisory panel seemed to be swayed by emotionally-charged accounts from parents and others who had lost loved ones to painkiller addictions. If FDA accepts the advisory panel's recommendation, it will be sent for review to officials at HHS. NACDS is coordinating efforts with patient groups to meet with FDA and urge the agency not to accept the recommendation of the advisory panel.